# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

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|---|---|---|
| Date of mailing *(day/month/year)*<br>27 October 2011 (27.10.2011) | | |
| Applicant's or agent's file reference<br>ART053CIPPCT | IMPORTANT NOTICE | |
| International application No.<br>PCT/US2010/031594 | International filing date *(day/month/year)*<br>19 April 2010 (19.04.2010) | Priority date *(day/month/year)*<br>17 April 2009 (17.04.2009) |
| Applicant<br>ARTHROSURFACE INCORPORATED et al | | |

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

| | | |
|---|---|---|
| Applicant's or agent's file reference<br>ART053CIPPCT | **FOR FURTHER ACTION** | See item 4 below |
| International application No.<br>PCT/US2010/031594 | International filing date *(day/month/year)*<br>19 April 2010 (19.04.2010) | Priority date *(day/month/year)*<br>17 April 2009 (17.04.2009) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 | | |
| Applicant<br>ARTHROSURFACE INCORPORATED | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the report |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☐ | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

| | |
|---|---|
| | Date of issuance of this report<br>18 October 2011 (18.10.2011) |
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br>Facsimile No. +41 22 338 82 70 | Authorized officer<br>Philippe Bécamel<br>e-mail: pt01.pct@wipo.int |

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: EDMUND PFLEGER
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# PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 09 JUN 2010 |
| Applicant's or agent's file reference<br>ART053CIPPCT | **FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2010/031594 | 19 April 2010 | 17 April 2009 |

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/56 (2010.01)
USPC - 606/79

Applicant ARTHROSURFACE INCORPORATED

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA/US | Date of completion of this opinion | Authorized officer: |
|---|---|---|
| Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | 24 May 2010 | Blaine Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/237 (cover sheet) (April 2007)

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/031594

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No. PCT/US2010/031594

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-20 | YES |
| | Claims | None | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-20 | NO |
| Industrial applicability (IA) | Claims | 1-20 | YES |
| | Claims | None | NO |

2. Citations and explanations:

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Tallarida et al. (hereinafter Tallarida) in view of Chudik.

Regarding claim 1, Tallarida discloses a system for repairing a defect on a portion of an articular surface of a patient (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system consistent with the present invention), said system comprising: a guide pin configured to be secured into said articular surface of said glenoid proximate to said defect (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically); an excision guide including a guide head and a guide sleeve disposed through said guide head (Para. [0108] In the embodiment shown in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...), wherein said guide head includes a contact surface configured to locate said excision guide relative to said articular surface (Para. [0108] Once the distal offset arm 112 has fully penetrated the incision and enters the site, shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A and advanced in-line with the reference axis 20A towards the implant target site; When compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working (reference) axis 20A used to define the implant geometry) and said guide sleeve is configured to receive said guide pin therethrough (Para. [0108] When compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113) and position said guide pin at an angle B relative to an axis generally normal and central to said defect on said articular surface (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry), wherein angle B is less than 90 degrees (Para. [0128] ...accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool); and an excision device (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), wherein said excision device includes a cannulated shaft and at least one cutter generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Para. [0110] and Fig. 16), wherein said cannulated shaft is configured to be advanced over said guide pin (Para. [0110] guide pin passes through a closely sized hole 116 in the cutting blade), but fails to explicitly disclose the system at the patient's glenoid and wherein said at least one cutter is configured to form a generally hemi-spherical excision site in said articular surface. However Chudik teaches a system for shoulder replacement surgery (Chudik Abstract) at the patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft ) wherein said at least one cutter is configured to form a generally hemi-spherical excision site in said articular surface (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Tallarida to include repair of a defect at a patient's glenoid wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 2, Tallarida in view of Chudik discloses the system of claim 1. Tallarida fails to explicitly disclose the system wherein angle B is selected to avoid contact with a corresponding humerous. However Chudik teaches a system for shoulder replacement surgery (Chudik Abstract) wherein angle B is selected to avoid contact with a corresponding humerous (Chudik Para. [0116] the transhumeral protective sheath 38 of the present invention provides protection for the bone within which the transhumeral portal sits). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Tallarida to protectively insert an implement in an arthroscopic resurfacing to avoid damage to bone tissue as taught by Chudik for the purpose of avoiding undesired damage to surrounding tissues in the area of resurfacing.

Regarding claim 3, Tallarida in view of Chudik discloses the system of claim 1. Tallarida further discloses the system wherein angle B is in the range of 10 degrees to 90 degrees (Para. [0128] ...accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2010/031594

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 4, Tallarida in view of Chudik discloses the system of claim 1. Tallarida further discloses the system wherein angle B is in the range of 10 degrees to 30 degrees (Para. [0128]).

Regarding claim 5, Tallarida in view of Chudik discloses the system of claim 1. Tallarida further discloses the system wherein said guide sleeve is configured to radially offset a point of entry of said guide pin into said articular surface from said axis (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry).

Regarding claim 6, Tallarida in view of Chudik discloses the system of claim 1. Tallarida further discloses the system wherein said excision guide further includes an excision guide arm affixed to said guide head and a handle affixed to said guide arm (Para. [0108] ...in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...).

Regarding claim 7, Tallarida discloses a system for repairing a defect on a portion of an articular surface of a patient (Abstract and Para. [0098]; Fig. 1), said system comprising: a guide pin configured to be secured into said articular surface of said glenoid proximate to said defect (Para. [0019]); an impact guide (Para. [0108]) including: an impact guide head having an upper portion and a lower portion, said lower portion configured to be received in a primary excision site of said articular surface (Para. [0108]), a guide notch defining a first opening through said impact guide head from said upper portion to said lower portion, wherein said guide notch is configured to receive said guide pin (Para. [0108]), and an impact device configured to be received in and extend through said impact slot to form a secondary excision site in said primary excision site (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), but fails to explicitly disclose the system at the patient's glenoid and an impact slot defining a second opening through said impact guide head from said upper portion to said lower portion. However Chudik teaches a system for shoulder replacement surgery (Chudik Abstract) at the patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft ). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Tallarida to include repair of a defect at a patient's glenoid as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a second impact element having a second opening, since a mere duplication of essential working parts of an invention involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 8, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact guide head includes a periphery and said first opening extends to said periphery (Para. [0110]).

Regarding claim 9, Tallarida in view of Chudik discloses the system of claim 7. Tallarida fails to explicitly disclose the system wherein said impact guide head is releasably coupled to an impact guide arm. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the arm and head separable, since making parts separate that were once integral involves only routine skill in the art and for the purpose of removing a cutting mechanism from the site of operation and thereby permit the insertion of other elements therein.

Regarding claim 10, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact guide head has a height Ht that corresponds to a height H of an implant configured to be received in said primary excision site (Para. [0106] guide pin 20 is removed and the knee 50 is articulated through its range of motion to ensure that the height of the radiused surface 31 of the hex-shaped cover 30 is proper, since the prosthetic surface 41 of the implant 40 is created also to be tangent to this radiused surface 31).

Regarding claim 11, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact guide head has a radius Rt that corresponds to a radius Ri of an implant configured to be received in said excision site (Para. [0110] This defines the radius that is effected as the instrument 120 is rotated around the guide pin 20, and corresponds to the overall diameter of the implant 40 that is delivered to the fully prepared site.).

Regarding claim 12, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact device includes a proximal end and a distal end (cutting blade 121), wherein the proximal end includes a striking surface and said distal end is configured to be received in and extend through said impact slot (Para. [0110]).

Regarding claim 13, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact device includes a chisel (Para. [0110] cutting blade 121).

Regarding claim 14, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact device is positioned at an angle Y relative to the impact guide arm (Paras. [0108] and [0110]), but fails to explicitly disclose the system wherein angle Y is in the range 0 degrees to 45 degrees. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a cutting device angled 0 to 45 degrees relative to an associated guide arm, since where the general conditions of a claims are discloses in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/031594

**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding claim 15, Tallarida in view of Chudik discloses the system of claim 7. Tallarida further discloses the system wherein said impact guide includes an impact guide arm and said impact device includes a proximal end and a distal end (Para. [0110] cutting blade 121), and said proximal end of said impact device is configured to be disposed generally parallel to said impact guide arm when said distal end is received in said impact slot (Paras. [0108] and [0110]).

Regarding claim 16, Tallarida discloses a method for repairing a defect on a portion of an articular surface of a patient (Abstract and Para. [0098]; Fig. 1), said system comprising: positioning an excision guide on said articular surface proximate to said defect (Paras. [0108] and [0110]), wherein said excision guide includes a guide head and a guide sleeve disposed through said guide head (Paras. [0108] and [0110]), wherein said guide head includes a contact surface configured to locate said excision guide relative to said articular surface (Paras. [0108] and [0110]); advancing a guide pin through said guide sleeve (Paras. [0108] and [0110]), wherein said guide sleeve is configured to receive said guide pin therethrough and position said guide pin at an angle B relative to an axis generally normal and central to said defect on said articular surface, wherein angle B is less than 90 degrees (Paras. [0108], [0110] and [0128]); securing said guide pin to said articular surface (Paras. [0108] and [0110]); and advancing an excision device over said guide pin, wherein said excision device includes a cannulated shaft and at least one cutter generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Paras. [0108] and [0110]), but fails to explicitly disclose the repair at a patient's glenoid and advancing to form a generally hemispherical primary excision site in said articular surface. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) at the patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft ) and advancing to form a generally hemispherical primary excision site in said articular surface (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect at a patient's glenoid wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 17, Tallarida in view of Chudik discloses the method of claim 16. Tallarida fails to explicitly disclose the method further comprising forming a secondary excision site within said generally hemi-spherical primary excision site. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a secondary excision site at the site of operation, since a mere duplication of essential working process elements involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 18, Tallarida in view of Chudik discloses the method of claim 17. Tallarida fails to explicitly disclose the method further positioning a portion of said implant into said secondary excision site. It would have been obvious to one of ordinary skill in the art at the time of the invention to include positioning in a secondary excision site, since a mere duplication of essential working process elements involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 19, Tallarida in view of Chudik discloses the method of claim 16. Tallarida discloses the method further comprising advancing an impact guide over said guide pin into said generally hemispherical primary excision site (Paras. [0108] and [0110]), wherein said impact guide includes an impact guide head, a guide notch defined in said impact guide head and an impact slot defined in said impact guide head (Paras. [0108] and [0110]), wherein said guide notch is configured to receive said guide pin (Paras. [0108] and [0110]); and advancing an impact device through said impact slot (Paras. [0108] and [0110]), but fails to explicitly disclose the method including advancing to form a secondary excision site in said primary excision site. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) including advancing to form a secondary excision site in said primary excision site (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 20, Tallarida in view of Chudik discloses the method of claim 16. Tallarida fails to explicitly disclose the method wherein angle B is selected to avoid contact with a corresponding humerous. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) wherein angle B is selected to avoid contact with a corresponding humerous (Chudik Para. [0116] the transhumeral protective sheath 38 of the present invention provides protection for the bone within which the transhumeral portal sits). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to protectively insert an implement in an arthroscopic resurfacing to avoid damage to bone tissue as taught by Chudik for the purpose of avoiding undesired damage to surrounding tissues in the area of resurfacing.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.